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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,263	12/28/2001	Akira Matsumori	2001-1881A	1315

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,263	MATSUMORI, AKIRA	
	Examin r	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT/JP00/04286, filed June 28, 2000. this application also claimed priority to Japan 185297/1999, filed June 30, 1999.

Applicant's amendments filed April 8, 2003 have been entered.

The addition of claim 36 in amendments filed April 8, 2003 is acknowledged.

The outstanding rejection under 35 USC 112 is withdrawn in view of the amendments filed April 8, 2003.

Upon reconsideration, the outstanding rejection under 35 USC 103 is withdrawn.

New ground of rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diseases induced by viruses page 5, lines 2-5, does not reasonably provide enablement for viral diseases induced by other viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the instant specification fails to provide provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when

assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

The claims are very broad. They encompass all viral diseases that are inducible by viruses capable of causing myocarditis. Applicant fails to set forth the criteria that define such viral conditions in the specification. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these conditions as claimed. Only a limited number of "viral disease" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the disorders being treated. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on ***all*** "viral disease(s) induced by viral myocarditis", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 - 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (WO 98/37875, its English traslation US Patent 6,277,888 is provided in the IDS received March 27, 2002) in view of Merck (The Merck Manual, 16th ed., 1992, page 2370-2371).

Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt is useful in treating viral hepatitis such as hepatitis B, non-A/non-B hepatitis (See col. 2, lines 37-38; col. 5, line 28-39). Sakai et al. also teaches that the herein claimed compound is useful as treating infectious diseases caused by pathogenic microorganisms (see col. 4, line 27-28; also col. 5, lines 41-44). Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating necrosis induced by toxin or the viral hepatitis (See col. 5, line 38). Sakai et al. teaches 2-amino-

2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating eye disease such as conjunctivitis (See col. 4, lines 51-59).

Sakai et al. does not expressly teach 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral myocarditis or ameliorating viral cytotoxicity. Sakai et al. does not expressly teach 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral diseases caused by orthomyxovirus or picornavirus.

Merck teaches conjunctivitis can be caused by enterovirus, which belongs to the family of picornavirus (See page 2370).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis or to ameliorate viral cytotoxicity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral diseases caused by orthomyxovirus or picornavirus.

One of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis or to ameliorate viral cytotoxicity. 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is known to be useful in treating hepatitis B infection (i.e., viral infection caused by hepatitis B virus in the liver). Therefore, employing 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral myocarditis caused by hepatitis B virus, which is viral infection caused by hepatitis B virus in the heart muscle, would have been reasonably expected to be effective since the causative agent is hepatitis B virus and

the herein claimed compound is effective against necrosis caused by such virus, regardless of the site of infection, absent evidence to the contrary. Moreover, treating the infection caused by hepatitis B virus would reasonably expected to ameliorate the viral cytotoxicity caused by the same virus.

One of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral diseases caused by orthomyxovirus or picornavirus. Since the herein claimed compound is known to be useful in treating conjunctivitis, which is a condition caused by picornavirus (conjunctivitis), employing the herein claimed compound in treating diseases caused by picornavirus would be reasonably expected to be useful.

Response to Arguments

Applicant's arguments filed April 8, 2003 averring Sakai's failure to suggest the herein claimed compounds in treating viral myocarditis have been fully considered but they are not persuasive. As discussed above, the effectiveness of the herein claimed compound in reducing the necrosis caused by the viral infection and/or toxin is known. Therefore, possessing the teaching of Sakai et al., one of ordinary skill in the art would have been reasonably expected to employ the herein claimed compound to reduce the damage done by the virus, thereby treating the condition (myocarditis). Examiner notes that treating viral diseases does not necessarily means eradicating the etiology. Therefore, by reducing the damage caused by the virus, the treatment method as claimed is practiced.

Applicant's submission of Miyamoto et al. along with the amendments filed April 8, 2003 have been considered. Miyamoto et al. demonstrates FTY's effectiveness in reducing necrosis, which is an expected result from Sakai et al.

Applicant's arguments averring hepatitis B virus is actually DNA virus and therefore, would be different from picornavirus and orthomyxovirus, which are RNA virus have been considered moot in view of the new ground of rejections set forth in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui AU1617
June 19, 2003